

10

Docket No. USF-T171X  
Serial No. 09/674,254Remarks

Claims 41-85 are pending in the subject application. Applicant gratefully acknowledges the Examiner's withdrawal of the objection and the rejections under 35 USC §101 and 35 USC §112, second paragraph, and the Examiner's indication that claim 70 is allowed. By this Amendment, Applicant has canceled claims 83 and 84 without prejudice and added new claims 86 and 87. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 41-82 and 85-87 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicant respectfully requests withdrawal of the finality of the outstanding Office Action. Applicant respectfully asserts that Applicant's Amendment submitted January 23, 2004 did not necessitate the new rejection of claim 72 for obviousness-type double patenting over U.S. Patent No. 6,649,588 set forth in the instant Office Action. Claim 72, prior to Applicant's January 23 Amendment, recited decreasing the level of expression of an *ebaf* nucleic acid, *etc.* in a female animal. Claim 72, even as amended by the January 23 Amendment, is directed to the same. Therefore, Applicant respectfully asserts that the amendments to claim 72 submitted in the January 23 Amendment did not necessitate the new grounds of rejection of claim 72. Accordingly, reconsideration and withdrawal of the finality of the rejections is respectfully requested.

Under section 6 of the Office Action, the Examiner has addressed Applicant's claim to the benefit of the effective filing date of U.S. application Serial No. 08/919,421 (hereinafter the '421 application). The Examiner has indicated that the subject application is not entitled to a claim of priority to the '421 application on the grounds that priority to the '421 application was "not granted by the PCT searching authority" during the international phase of the subject application and, therefore, priority cannot be granted by the U.S. Patent Office. The Examiner also states that "the instant Application was filed as a National Stage Application under 35 USC 371, not 37 CFR 1.111" (Applicant assumes for purposes of these remarks that the Examiner intended to indicate "35 USC 111," rather than "37 CFR 1.111"). From the statements in the Office Action, the Examiner appears to assume that Applicant has made a claim of priority under the Paris Convention Treaty. However, Applicant is not making a claim of priority to the '421 application under the Paris Convention.

11:\doc\ptv\amd\USF-T171X.final.after.rec.doc\DNB/sl

11

Docket No. USF-T171X  
Serial No. 09/674,254

Applicant is claiming the benefit of the filing date of an earlier application under 35 USC §120 of the United States Patent Statute; nowhere in Applicant's comments in the January 23 Amendment regarding the claim to the '421 application did Applicant refer to a "claim of priority." Because Applicant is not making a claim of priority to the '421 application under the Paris Convention Treaty, the rules associated with the Paris Convention regarding a claim of priority to an earlier application are not pertinent in this matter. The relevant statute and rules are 35 USC §120 and 37 CFR 1.78, respectively. The Examiner's attention is directed to MPEP 1893.03(c), relevant portions of which are reprinted below.

A national stage application may include a priority claim under 35 U.S.C. 119(c), or 120 and 365(c) to a prior U.S. national application or under 35 U.S.C. 120 and 365(c) to a prior international application designating the U.S. The conditions for according benefit under 35 U.S.C. 120 are as described in MPEP § 201.07, § 201.08, and § 201.11 and are similar regardless of whether the U.S. national application is a national stage application \*submitted under 35 U.S.C. 371 or a national application filed under 35 U.S.C. 111(a).

In order for a national stage application (of international application "X") to obtain benefit under 35 U.S.C. 120 and 365(c) of a prior filed copending nonprovisional application or prior filed copending international application designating the United States of America, the national stage application must comply with the requirements set forth in 37 CFR 1.78(a)(1) through 37 CFR 1.78(a)(3). The prior nonprovisional application or international application must name as an inventor at least one inventor named in the later filed international application "X" and disclose the named inventor's invention claimed in at least one claim of the national stage application in the manner provided by the first paragraph of 35 U.S.C. 112. The national stage application must contain a reference to the prior nonprovisional or international application (either in an application data sheet (37 CFR 1.76) or in the first sentence of the specification), identifying it by application number (series code and serial number) or international application number and international filing date and indicating the relationship of the applications.

A prior filed nonprovisional application is copending with the national stage application if the prior U.S. national application was pending on the international filing date of the national stage application.

\\:\doc\pto\Amd\USP-T171X.final.after.rce.doc\1\NB\sl

12

Docket No. USF-T171X  
Serial No. 09/674,254

Accordingly, Applicant again asserts for the subject application a claim to the benefit of the effective filing date of U.S. Application No. 08/919,421 (which was filed August 27, 1997 and issued as U.S. Patent No. 5,916,751 on June 29, 1999), which claims the benefit of U.S. provisional Application No. 60/025,800, filed August 27, 1996 (thus, the effective filing date of the '421 application is August 27, 1996). As noted above, this benefit claim is made under 35 USC §120. Applicant refers the Examiner to the "Cross-Reference to Related Applications" section at page 1, lines 6-9, of the subject specification. Applicant's benefit claim (not a claim of priority under the Paris Convention Treaty) to the '421 application was present in the subject application as filed and has not been canceled by any previous amendments (as acknowledged by the Examiner in the instant Office Action). Although there may have been a punctuation error in the "Cross-Reference to Related Applications" section set forth at page 1, lines 3-9, of the subject specification, it has been clear from the filing of the subject application that Applicant intended that the subject application was a continuation-in-part application of the '421 application. Applicant notes that as long as the '421 application was co-pending with PCT application No. PCT/US99/09366 (filed April 29, 1999), which it was, and shared at least one co-inventor with the subject application, which it does, then the subject application (a national stage of PCT application No. PCT/US99/09366) can claim the benefit of the filing date of the '421 application, regardless of whether priority to the '421 application was granted under the PCT and regardless of whether the application was filed under 35 USC §371 or 35 USC §111 (as noted above in the text from MPEP 1893.03(c), an application can be filed under 35 USC §371 and still claim the benefit of an earlier filed U.S. application, e.g., as a continuation-in-part of the earlier filed application). Applicant also notes that the subject application currently names Siamak Tabibzadeh as the inventor of the claimed subject matter and that Siamak Tabibzadeh is also named as an inventor on each of the applications listed in the "Cross-Reference to Related Applications" section.

To summarize, the subject application is a national stage application of PCT application No. PCT/US99/09366 which was filed April 29, 1999. Thus, April 29, 1999 is the actual filing date of the subject application. The '421 application was pending from August 27, 1997 to June 29, 1999; thus, the subject application was pending during the pendency of the '421 application. In addition, Siamak Tabibzadeh is named as an inventor on both the subject application and the '421 application.

H:\doc\pto\Amd\USF-T171X.final.after.rec.doc/DNB/sl

13

Docket No. USF-T171X  
Serial No. 09/674,254

As can be understood from the above, the subject application has continuity of pendency and inventorship with the '421 application and, therefore, the subject application is entitled to claim the benefit of the '421 application under 35 USC §120.

Accordingly, Applicant has amended the "Cross-Reference to Related Applications" section of the subject application to correct the punctuation error in the appropriate benefit claim and to indicate the relation of the applications as required under 37 CFR 1.78. Applicant respectfully asserts that this amendment should be permitted because the subject specification already included a cross-reference to the '421 application (and U.S. provisional application Serial No. 60/025,800) and because the subject application entered the national stage from International patent Application No. PCT/US99/09366 which was filed April 29, 1999, which is well before the November 29, 2000 date specified in 37 CFR 1.78(a)(ii)(C). Thus, the "Cross-Reference to Related Applications" amendment can be made at this time. If the Examiner requires further clarification regarding Applicant's claiming the benefit of the filing date of the '421 application under 35 USC §120, Applicant respectfully requests that the Examiner contact Applicant's undersigned representative to resolve this issue.

At section 10 of the Office Action, the Examiner has indicated that claims 81-85 are withdrawn from further consideration as being directed to a non-elected invention. The Examiner asserts that claims 81-85 recite "components contained in compositions not previously considered on the record . . ." As indicated above, Applicant has canceled claims 83 and 84. However, Applicant traverses this restriction in regard to claims 81, 82, and 85. Applicant respectfully asserts that claims 81, 82, and 85 are directed to the elected invention and should be considered in the examination of the subject application. Applicant notes that claims 81, 82, and 85 depend from claim 72 or 73 and recite species of the generic composition set forth in claims 72 and 73 (the Examiner acknowledges that claims 72 and 73 are directed to the elected invention). Applicant also notes that the Examiner has rejected claims 72 and 73 as nonenabled on the grounds that the claims 72 and 73 do not recite specific reagent components, yet dependent claims 81-85, which do recite specific reagent components, are restricted out as being directed to a non-elected invention. No restriction requirement specifying restriction of the reagent components or requiring an election of a particular component was ever made in the subject application. If a group of a component was restricted, either

11:\doc\pio\amd\USF-T171X.final.after.rec.doc\DNB\sl

14

Docket No. USF-T171X  
Serial No. 09/674,254

by written Restriction Requirement or via telephonic conference, Applicant respectfully requests that the Examiner clarify which reagent component the Examiner believes was actually or constructively elected. Moreover, in regard to claims 81 and 82 (which are directed to use of an antibody that binds to a protein encoded by an *ebaf* nucleic acid), Applicant notes that currently pending claims 64 and 65, directed to an antibody to an *ebaf*-encoded protein, are of record and currently under consideration by the Examiner in the subject application. In regard to claim 85, the claim recites that the composition used in the method of claim 73 comprises a protein encoded by an *ebaf* nucleic acid. Numerous other claims of the elected invention recite a "protein encoded by an *ebaf* nucleic acid." For example, claim 74 is directed to a kit comprising "a protein encoded by an *ebaf* nucleic acid." Thus, Applicant respectfully asserts that the reagent components of claims 81, 82, and 85 have previously been considered on the record. Accordingly, reconsideration and withdrawal of the restriction as to claims 81, 82, and 85 is respectfully requested.

Claims 72 and 73 are rejected under 35 USC §112, first paragraph, as nonenabled by the subject specification. The Examiner asserts that the composition being administered is described by function only, and does not recite any specific reagent components or elements with the recited biological function. Applicant respectfully asserts that the claims are enabled by the subject specification. Claims 72 and 73 recite that a composition is administered to the female animal that decreases or increases levels of *ebaf* nucleic acid or *ebaf* protein, or that decreases or increases production or biological activity of *ebaf* protein. The subject specification teaches examples of compositions that exhibit the recited function. The composition can comprise, for example, an *ebaf* protein, an antibody that binds to an *ebaf* protein and blocks activity, or a nucleic acid that is antisense to *ebaf*. Dependent claims 81, 82, and 85 recite specific elements of a composition that can be used in the claimed invention. Thus, generic claims 72 and 73 are supported by the teachings in the specification of several species of compositions that can be used in the claimed methods. Enablement of a generic claim does not require that the specification explicitly teach each and every species of the claimed genus. *In re Angstadt*, 190 USPQ 214, 218 (CCPA 1976). Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

H:\doc\pto\Amd\USF-T171X.final.after.rec.doc\DNB/sl

15

Docket No. USF-T171X  
Serial No. 09/674,254

Claims 72 and 73 are also rejected under 35 USC §112, second paragraph, as indefinite on the grounds that the claims do not recite what components are in the composition administered to the female animal in the claimed methods. Applicant respectfully asserts that the claims as filed are definite. Claims 72 and 73 recite that a composition that decreases or increases levels of *ebaf* nucleic acid, or *ebaf* protein, or the production or biological activity of *ebaf* protein, is administered to the female animal. As noted above in Applicant's comments regarding the §112, first paragraph, rejection, several species of the generic composition are described in the subject specification (and in claims 81-85) that can be used in the claimed methods. Any composition that functions as required in the claims can be used and several examples have been provided. Thus, a skilled artisan would understand the metes and bounds of the claims. By this Amendment, Applicant has presented new claims 86 and 87, which correspond to claim 72 combined with claim 81 and claim 73 combined with claim 85, respectively, and that recite a specific component that is utilized in the claimed method to increase (claim 86) or decrease (claim 87) fertility of a female animal. Entry and consideration of claims 86 and 87 is respectfully requested. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 41-69 and 71 are rejected under 35 USC §102(b) as anticipated by Tabibzadeh *et al.* (U.S. Patent No. 5,916,751, which issued from the '421 application). In addition, claims 74-80 are rejected under 35 USC §103(a) as obvious over Tabibzadeh *et al.* (U.S. Patent No. 5,916,751). In the Office Action dated October 23, 2003, the Examiner asserted that the Tabibzadeh *et al.* patent discloses detecting or diagnosing endometrial irregularity in a female, including the screening of endometrial tissue or blood for abnormal levels of *ebaf* nucleic acid or proteins. Applicant notes that in the October 23, 2003 Office Action, the Examiner relied on the incorporated Kothapalli *et al.* reference as teaching that *ebaf* expression is associated with endometrial bleeding (however, Applicant notes that the Kothapalli *et al.* reference is not explicitly indicated as being relied on in the current rejections). The Examiner also stated that the Tabibzadeh *et al.* patent discloses the utilization of nucleic acid detection and protein detection kits for the determination of *ebaf* nucleic acid expression and/or *ebaf* protein/peptide biological activity in a biological sample. In regard to the obviousness rejection, the Examiner concluded that it would have been obvious to the ordinarily skilled artisan to formulate the necessary reagents for the determination, detection or diagnosis of an

H:\doct\ptol\Amd\USF-T171X.final.after.rec.doc\DNV\sl

16

Docket No. USF-T171X  
Serial No. 09/674,254

ebaf-related condition in view of the teachings of the Tabibzadeh *et al.* patent. Applicant assumes, in view of the rejection under 35 USC §102(b), that the Tabibzadeh *et al.* patent relied upon for the §103 rejection is being applied as a §102(b) reference by the Examiner for purposes of the §103 rejection.

In response to Applicant's Amendment submitted January 23, 2004, the Examiner rejected Applicant's traversal of the rejections on the grounds that Applicant's priority claim to the '421 application "has not been granted by either the PCT searching authority, nor the US-PTO" and, therefore, the Tabibzadeh *et al.* patent is "appropriately applied as prior art." Applicant respectfully traverses the rejections under 35 USC §102(b) and 35 USC §103(a).

As an initial matter, Applicant notes that the subject application (even without the benefit of the filing date of the '421 application) has an actual filing date of April 29, 1999. The Tabibzadeh *et al.* patent (U.S. Patent No. 5,916,751) issued on June 29, 1999 which is after the April 29, 1999 filing date of the subject application. A reference only qualifies as prior art under 35 USC §102(b) if the reference was published more than one year before the filing date of a patent application. Thus, the Tabibzadeh *et al.* patent does not qualify as prior art under 35 USC §102(b)/35 USC §103 against the subject application. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §102(b) and 35 USC §103(a) is respectfully requested.

Although the rejections in the Office Action are under 35 USC §102(b)/103, Applicant also submits the following comments in the event the Examiner would make a rejection under 35 USC §102(c). Applicant hereby incorporates the remarks presented herein in regard to Applicant's claim to the benefit of the filing date of the '421 application for the subject application. As noted above, the subject application claims the benefit of the effective filing date of the '421 application (*i.e.*, August 27, 1996, the filing date of provisional application No. 60/025,800) under 35 USC §120. The Tabibzadeh *et al.* patent applied under the §102/§103 rejections issued from the '421 application. Applicant further notes that the Kothapalli *et al.* reference was apparently published sometime in or around May 1997 which is after the August 27, 1996 filing date of the 60/025,800 provisional application. In view of Applicant's claim to the benefit of the August 27, 1996 filing date of the '421 application, Applicant respectfully asserts that the Tabibzadeh *et al.* patent that

H:\doc\pto\Amd\USF-T171X.final.after.rev.doc/DNI\sl

17

Docket No. USF-T171X  
Serial No. 09/674,254

issued from the '421 application is not effective prior art against the subject application under 35 USC §102(e).

Claims 49-51 are rejected under the judicially created doctrine of "obviousness-type" double patenting over claims 1 and 7 of U.S. Patent No. 6,294,662. Applicant respectfully asserts that the claims are not obvious over the cited patent. However, Applicant acknowledges that a terminal disclaimer can be filed to overcome this rejection and is prepared to submit an appropriately executed terminal disclaimer upon the Examiner's indication that claims 49-51 would be allowable but for the rejection of these claims for obviousness-type double patenting.

Claim 72 is rejected under the judicially created doctrine of "obviousness-type" double patenting over claims 1, 5, 14, and 15 of U.S. Patent No. 6,649,588 (hereinafter the '588 patent). Applicant respectfully asserts that claim 72 is not obvious over claims 1, 5, 14, and 15 of the cited patent. The '588 patent has a filing date of October 5, 2000 and issued on November 18, 2003. The subject application is a U.S. national stage application of PCT application No. PCT/US99/09366, filed April 29, 1999. Thus, the '588 patent is not prior art to the subject application. Moreover, claim 1 of the '588 patent is directed to contacting tissue expressing TGF- $\beta$  with an *ebaf* protein to inhibit TGF- $\beta$  activity whereas claim 72 of the subject application is directed to decreasing expression or activity of an *ebaf* protein in an animal in order to increase the fertility of the animal. Applicant notes that claims 5, 14, and 15 of the '588 patent all depend directly or indirectly from claim 1. The claims in the '588 patent do not teach or suggest anything regarding decreasing *ebaf* activity to increase fertility. Accordingly, Applicant respectfully asserts that claim 72 is not obvious over the claims of the '588 patent. Reconsideration and withdrawal of the rejection is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant's agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

H:\doc\pt\Amd\USF-T171X.final after rec.doc/DNB/sl



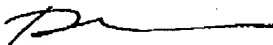
18

Docket No. USF-T171X  
Serial No. 09/674,254

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Doran R. Pace  
Patent Attorney  
Registration No. 38,261  
Phone No.: 352-375-8100  
Fax No.: 352-372-5800  
Address: 2421 N.W. 41st Street, Suite A-1  
Gainesville, FL 32606-6669

DRP/sl

11:\doc\p\to\Amr\USF-T171X.final.after.rce.doc\DNB/sl